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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,462	08/14/2006	Yukiko Inamoto	2006_1261A	7229

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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,462	INAMOTO ET AL.	
	Examiner	Art Unit	
	SAVITHA RAO	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/18/2009 and 03/04/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 4-6 are pending.

Receipt and consideration of Applicants' amended claim set and remarks/arguments filed on 02/18/2009 is acknowledged.

Applicants' arguments, filed on 02/18/2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102(b)

Rejection

These rejections are necessitated by the newly submitted claims filed on 02/18/2009

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Konishi et al (EP 0784975 referenced in the IDS) as evidenced by Reller (US 4219548).

Konishi et al. discloses a drug for the treatment of skin injuries, particularly hardly

curable diseases such as bedsore, which comprises as an active ingredient acetylsalicylic acid and the drug is used in the form of a topical preparation for external application (abstract, claims 1-4)). Konishi discloses that the topical preparation of his invention contains 0.05 to 15% by weight of acetylsalicylic acid bases on the whole weight of the preparation (page 3, lines 10-14, claim 3). Konishi discloses an example 1-10 which gives various topical formulations comprising acetylsalicylic acid ranging from 0.05% (example 8) to 15% (example 7) by weight (page 4, line 10 to page 7, line 15). Konishi also discloses a method for the treatment of skin injuries, especially hardly curable diseases such as bedsore by applying a topical preparation comprising acetylsalicylic acid to the injured region of the skin (page 2, lines 47-50). Konishi discloses a method of treatment of rats which were injured using a flatiron heated at 200°C for 5 seconds (experiment 2, on page 9) which would generate in a skin wound due to temperature impairment with acetylsalicylic acid in the form of an ointment. The new claim 4 is accordingly anticipated by Konishi et al.

Reller is being provided as a supplemental reference to demonstrate the routine knowledge in using acetylsalicylic acid as active ingredient in topical composition that is useful for the treatment of inflammation of skin including dermatoses accompanied by inflammation, skin injury, contact burns and insect bites (see column 1, lines 18-43; column 1, line 66 through column 2, line 3; Example I-II). Particularly, Example II teaches that topical administration of aspirin is useful in reducing inflammation and the sensation of itching and pain.

Accordingly claims 4-6 are anticipated by Konishi et al.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Inamoto et al (US 2003/0125308 an English equivalent of WO2001/047525, referenced in the instant IDS) as evidenced by Reller (US 4219548).

Inamoto discloses external preparations having an excellent antipruritic activity acetylsalicylic acid as an active ingredients and a method of treating pruritis by using said external preparations [0001]. Inamoto discloses that acetylsalicylic acid (aspirin) has a strong analgesic activity, antifebrile activity and an antirheumatic activity being less on its side effects and superior in its safety [0006]. Inamoto also discloses that a new use of acetylsalicylic acid in the form of an external preparation, ointments for treating neuralgia and external preparations for treating skin injury and a transdermal administration system for treatment of thrombosis and prophylactic treatment of cancer has been illustrated in prior art [0008]. Inamoto discloses that the amount of acetyl salicylic acid in the external preparation depends on form of the preparation bus is 0.05-80%, preferably 0.05-70%, ,more preferably 0.1-50% per total amount by weight. Inamoto additionally discloses that if the aspirin amount is greater than 80% by weight, it is impossible to maintain the physical property of an external preparation and when it is less than 0.05% by weight, there is not enough antipruritic activity and therefore the amount of more than 80% or less than 0.05% is not preferable [0014]. Inamoto further provides examples of external formulations comprising acetylsalicylic acid (examples 1-25, Tables 1-4, [0027-0030]). Inamoto finally teaches that the preparation as per his invention is applied to the lesion [0025].

"Though it is noted that Inamoto does not administer his inventive compounds to specifically treat skin wounds selected from the group consisting of traumata, infectious diseases in surgery, postoperative wound, temperature impairment, chemical impairment, radiation injury etc, the teaching by Inamoto of the method of administration of an effective dose of the medicine containing acetylsalicylic acid, is the same as the method currently claimed, and thus anticipates the instant claims. It is also noted that "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). As such the instantly claimed mechanistic functions of the compounds to treat a person with specific type of skin wounds would be present in the identical composition of acetylsalicylic acid by Inamoto and would therefore elicit these effects whenever it is administered. Therefore the method performed by Inamoto anticipates the instant claims.

Reller is being provided as a supplemental reference to demonstrate the routine knowledge in using acetylsalicylic acid as active ingredient in topical composition that is useful for the treatment of inflammation of skin including dermatoses accompanied by inflammation, skin injury, contact burns and insect bites (see column 1, lines 18-43; column 1, line 66 through column 2, line 3; Example I-II). Particularly, Example II teaches that topical administration of aspirin is useful in reducing inflammation and the sensation of itching and pain.

Accordingly claims 4-6 are anticipated by Inamoto et al.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being as being unpatentable over Mizobuchi et al. (US 6268355 B 1) as evidenced by Reller (US 4219548).

Mizobuchi discloses a stable external preparation consisting essentially of acetylsalicylic acid and carriers (i.e., white vaseline, yellow vaseline, lanolin, purified bee wax, cetanol, steryl alcohol, stearic acid, hydrogenated oil, hydrocarbon gel, polyethylene glycol, liquid paraffin and squalane), wherein said preparation is formulated in the form of cataplasms, plasters, ointments, creams, external powders (col.3, line 30 to clol.4 lines 43 and examples 1-32) and the amount of aspirin as an active ingredient in an external preparation is 0.001 to 30% by weight per total amount, preferably 0.01 to 20% by weight, more preferably 0.05 to 15% by weight (column 2, lines 15-26 and 58-60;). Mizobuchi teaches that said composition is superior in stability and transdermal absorption from skin (column 2, lines 6-10 and 61-65; column 12, lines 65-67); and that said composition having anti-inflammatory antipyretic analgesic is useful in enhancing healing of skin injury (Figure 1 and Experiment 4). Mizubuchi discloses treatment of rats injured with the ointment of his invention comprising acetylsalicylic acid as the active ingredient (experiment 4, col.9, lines 25-46).

“Though it is noted that Mizobuchi does not specifically administer his inventive compounds to treat skin wounds selected from the group consisting of traumata, infectious diseases in surgery, postoperative wound, temperature impairment, chemical impairment, radiation injury etc, Mizobuchi does teach treatment of an injury with the

instantly claimed compound and also teaches the method of administration of an effective dose of the medicine containing acetylsalicylic acid, is the same as the method currently claimed, and thus anticipates the instant claims. It is also noted that "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). As such the instantly claimed mechanistic functions of the compounds to treat a person with specific type of skin wounds would be present in the identical composition of acetylsalicylic acid by Mizobuchi and would therefore elicit these effects whenever it is administered. Therefore the method performed by Mizobuchi anticipates the instant claims.

Reller is being provided as a supplemental reference to demonstrate the routine knowledge in using acetylsalicylic acid as active ingredient in topical composition that is useful for the treatment of inflammation of skin including dermatoses accompanied by inflammation, skin injury, contact burns and insect bites (see column 1, lines 18-43; column 1, line 66 through column 2, line 3; Example I-II). Particularly, Example II teaches that topical administration of aspirin is useful in reducing inflammation and the sensation of itching and pain.

Accordingly claims 4-6 are anticipated by Mizobuchi et al.

Response to Applicant's argument submitted on 02/18/2009

In light of the new grounds of rejection above, the arguments submitted on 02/18/2009 which was for the previously submitted rejection is moot.

However, examiner has considered Applicant's argument and does not find it persuasive.

Applicant argue that Konishi et al does not disclose treatment of a skin wound selected from the group recited in instant claim 4. Examiner would like to point out that Konishi indeed teaches method of topical administration of an effective dose of acetylsalicylic acid to rats injured by temperature (see rejection above) which anticipates the skin wound due to temperature impairment recited in instant claim 4.

Applicant argues that Reller et al, Inamoto et al and Mizubuchi et al do not disclose treatment of a skin wound selected from the group consisting of traumata, infectious diseases in surgery, postoperative wound, temperature impairment, chemical impairment, radiation injury etc. However all the three references teaches the method of administration of an effective dose of the medicine containing acetylsalicylic acid to a subject which is the same as the method currently claimed, and thus anticipates the instant claims. It is also noted that “Products of identical chemical composition can not have mutually exclusive properties.” A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). As such the instantly claimed mechanistic functions of the topical acetylsalicylic acid to treat a person with specific type of skin wounds would be present in the identical compositions of acetylsalicylic

acid taught by either Reller or Inamoto et al or Mizobuchi et al. and would therefore elicit these effects whenever it is administered . Therefore the method performed by either Reller, Inamoto or Mizobuchi anticipates the instant claims.

Accordingly, the above rejections are maintained.

Conclusion

Claims 4-6 are rejected. No claims are allowed

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAVITHA RAO whose telephone number is (571)270-5315. The examiner can normally be reached on Mon-Fri 7.00 am to 4.00 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SAVITHA RAO/

Examiner, Art Unit 1614

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614